REMARKS

Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24-28, 31, 32, 35-46 and 54 are under consideration in this application. Claim 24 has been amended; claim 54 has been added. Support for the amendment can be found throughout the specification. Contrary to the assertion in the Advisory Action, literal support for the hybridization conditions recited in claim 54 can be found in Example 4 on page 33 of the specification. (See lines 17-22.)

No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is expressly stated that these amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 24-29, 31, 32 and 35-46 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description and enablement. The rejections are traversed.

The Office Action alleges on page 3 that "[a] description of the function of the enzyme does not satisfy the written description requirement for claims drawn to sequences exhibiting less than 100% sequence identity when compared to a specific SEQ ID NO." The Examiner's attention is drawn to Example 14 of the USPTO's "Synopsis of Application of Written Description Guidelines". Example 14 presents a fact pattern that is analogous with that of the instant application. The claim in Example 14 recites the structure of the claimed protein, in the form of a SEQ ID NO and variants with a particular percent identity to the recited sequence, and function in the form of identifying the reaction that the protein catalyzes (*i.e.* its enzymatic activity). Claim 24 of the instant application recites (1) structure of the claimed protein in the form of a SEQ ID NO, and variants having over 90% identity with the nucleic acid molecule

encoding the claimed protein and (2) function of the claimed protein in the form of its isoamylase activity.

The Office Action goes on to allege that "Applicant are not entitled to a genus when they only disclose one species." Firstly, it should be noted that Applicants have disclosed two wheat isoamylases (SEQ ID NO:3 and SEQ ID NO:7) and the nucleic acid sequences that encode them. Secondly, as discussed in Example 14, even if the claimed SEQ ID NO is the only species disclosed, it is representative of the genus because all members of the genus have the claimed level of identity with, and function of, the protein described by the reference sequence. In the case of the current application, however, not just one, but two members of the genus are disclosed, providing even more evidence than is necessary, according to Example 14 of the Written Description Guidelines, to meet the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner is also respectfully invited to review recently issued U.S. Patent Nos. 6,623,948, 6,617,143, 6,590,141 and 6,521,433, all of which contain claims with percent identity language applied to the entire claimed molecule, and not a particular domain.

Applicants have clearly provided relevant, identifying structural characteristics in the form of the nucleotide and amino acid sequences of two wheat isoamylases, and their enzymatic function is taught in the specification. There are reasonable limits regarding what the claimed nucleic acid molecules can comprise. The fact that they are not necessarily required to comprise the exact disclosed sequence does not render them inadequately described.

The Advisory Action reiterates the view that the recitations of "90% identity" and "part thereof" continue to raise §112 issues. While the Applicants disagree for the reasons stated above, in an effort to expedite prosecution, these phrases have been removed from claim 24.

With respect to enablement, claim 24 has been amended to remove the hybridization language. A nucleic acid molecule that hybridizes to the nucleic acid molecule of claim 24 is claimed in new claim 54, which recites specific hybridization conditions. These conditions are taught in Example 4, and were used to isolate the nucleic acid molecule of SEQ ID NO:6, encoding SEQ ID NO:7, which is a species of the genus claimed in claim 24. Further, claim 24 has been limited to nucleic acid molecules isolated from wheat, thereby addressing the "multitude of plants" concern expressed in the Office Action.

The Advisory Action alleged that claim 54, as presented in the Amendment filed on December 1, 2003 that was not entered, raised new §101, §112, and art issues. The word "isolated" has been added to claim 54, obviating any §101 issues.

With respect to §112, first paragraph, the claim clearly meets the written description guidelines. Firstly, claim 54 does not introduce new matter, as the conditions recited are literally taught on page 33 of the application. Secondly, the Examiner is invited to review Example 9 of the Written Description Guidelines, which is reproduced below.

> **Specification:** The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO:1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acides that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO:1.
>
> **Claim:** An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.
>
> **Analysis:** A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO:1 under highly stringent conditions and encodes a protein with apecific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.
>
> The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO:1 and must encode a protein with a specific activity.
>
> The search of the prior art indicates that SEQ ID NO:1 is novel and unobvious.
>
> There is a single species disclosed (a molecule consisting of SEQ ID NO:1) that is within the scope of the claimed genus.
>
> There is actual reduction to practice of the disclosed species.

> Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.
>
> **Conclusion:** The claimed invention is adequately described.

The facts described in Example 9 mirror the facts in the instant case, as will be discussed herein in detail.

The instant specification discloses SEQ ID NO:2, which encodes a wheat isoamylase enzyme. The specification includes an example (Example 4), wherein a portion of SEQ ID NO:2 was used under the claimed conditions for the isolation of SEQ ID NO:6. In Example 9 above, the hybridizing nucleic acid(s) were not even sequenced. As shown in Example 5 of the specification, SEQ ID NO:6 encodes a wheat isoamylase, represented by SEQ ID NO:7.

Claim 54 uses the language of the claim in Example 9 of the Written Description Guidelines, except that the hybridization conditions are recited specifically.

Hybridization techniques were well known in the art at the time of filing, and no evidence to the contrary has been presented or is on the record in this application.

Claim 54 is drawn to a genus of nucleic acids, all of which must hybridize with SEQ ID NO:2, or its complement, and must encode a protein with a specific activity, *i.e.* a wheat isoamylase. SEQ ID NO:2 is novel and unobvious. There are two species disclosed that are within the scope of the claimed genus: SEQ ID NO:2 and SEQ ID NO:6. There is actual reduction to practice of the disclosed species.

As discussed in the analysis section of Example 9 above, a person of skill in the art would not expect substantial variation among species encompassed within the scope of Claim 54, because the highly stringent hybridization conditions recited in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that Applicants were in possession of the invention claimed in claim 54. Therefore, claim 54 is adequately described.

Applicants maintain that limiting the claims to only the nucleotide sequence of SEQ ID NO:2 would unfairly narrow the scope of the invention. Applicants further assert that the requirements of the first paragraph of Section 112 have be met: two members of the genus claimed in claim 24 have been identified, using methods taught in Examples 1 and 4 of the application, and adequate structural and functional characteristics are recited in the claims. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

III. THE ART REJECTIONS ARE OVERCOME

Claims 24-28, 31, 32, 35-42 and 45 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kossmann *et al.* The rejection is traversed.

Kossman *et al.* relates to a soluble starch synthase and a starch granule-bound starch synthase from potato. Applicants reiterate that these are completely different enzymes than the wheat isoamylases of the instant invention. There is simply no way that the potato starch synthases of Kossman *et al.* can have "the function of a wheat isoamylase", as recited in the claims of the present application. Starch synthases catalyze a polymerization reaction, whereby a glucosyl residue of ADP-glucose is transferred to an α-1,4-glucan. Conversely, the enzymes of the present invention break down branchings of glycogen and amylopectin, as is taught in the paragraph bridging pages 2 and 3 of the application, refuting the contention in the Office Action that there is a "lack of definition for a wheat isoamylase". Furthermore, even if, as the Office Action alleges, the enzymes of Kossman *et al.* would hybridize with one of the claimed molecules under the conditions formerly claimed, and it is not admitted that they would, they still do not meet the limitation of being "a protein with the function of a wheat isoamylase", as required by the claims. Finally, the enzymes of Kossman *et al.* are not isolated from wheat, as is now recited in claim 24.

Claims 24-28, 31, 32 and 35-45 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Vasil *et al.* Claims 24-28, 31, 32 and 35-42 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Baltensperger *et al.* The rejections will be addressed collectively and are traversed.

For reasons discussed above, Kossmann *et al.* do not teach or suggest the claimed nucleic acid molecules. The enzymes of Kossman *et al.* are starch synthases, not debranching enzymes, and are isolated from potato, not wheat.

Vasil *et al.* and Baltensperger *et al.* do nothing to remedy the deficiencies of Kossman *et al.* Vasil *et al.* relates to a method for transforming wheat, however, the combination of references involving the transformation of wheat with a nucleic acid encoding a completely different enzyme from the current invention, would not result in the invention. Similarly, Baltensperger *et al.* claim a method for isolating starch from grain crops. In no way can Baltensperger *et al.* be combined with Kossmann *et al.* to arrive at the instant invention.

The Examiner is thanked for indicating on page one of the Advisory Action that the amendments and arguments presented in the December 1, 2003 Amendment and herein would overcome the art rejections.

Turning now to the assertion in the Advisory Action that claim 54 raises new art issues, this is simply not possible. Claim 54 represents a narrower embodiment of subject matter that was previously claimed in part (c) of claim 24. Hybridization language has been present in the claims since the day this application was filed; and, the recitation of more specific hybridization conditions should not necessitate a new search if the broader embodiment has already been searched properly, which Applicants assume is the case.

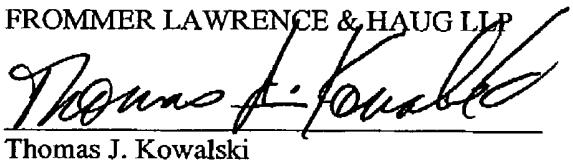
As the claimed invention is not taught or suggested by any of the cited references, alone or in combination, it cannot be anticipated by or obvious over them. Therefore, reconsideration and withdrawal of the rejections under Sections 102 and 103 are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper is requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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